DETAILED ACTION

Claim Objections

1. Claims 26, 31, and 39-51 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 14-16, and 32, drawn to polynucleotides, vectors and host cells comprising the same, kits comprising said polynucleotides, and a method for the recombinant production of the polypeptide encoded thereby.

Group II, claim(s) 11-13 and 33, drawn to polypeptides and kits comprising the same.

Group III, claim(s) 17, drawn to a method for determining the presence of a nucleic acid in a sample.

Group IV, claim(s) 18, drawn to a method for determining the presence of an antibody in a sample.

Group V, claim(s) 19, drawn to a method for determining the presence of a polypeptide in a sample.

Group VI, claim(s) 20-25, 27, and 34, drawn to antibodies and kits comprising the same.

Group VII, claim(s) 28-30, drawn to a bacteriophage comprising an antibody, bacterial cells comprising said bacteriophage, a recombinant host cell that produces an antibody, and a method for making antibodies.

Group VIII, claim(s) 36, drawn to a method for identifying an agent that modulates the activity of a polypeptide.

Group IX, claim(s) 37-38, drawn to a compound of undisclosed constitution that modulates the activity of a polypeptide.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. § 1.475(B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, an isolated nucleic acid molecule, and the first recited use of the nucleic acid molecule. Because the technical features of the Groups II-IX inventions is not present in the Group I claims, unity of invention is lacking. Furthermore, the polynucleotides of Group I, the polypeptide of Group II, the antibodies of Group VI, and the compounds of undisclosed constitution that modulate the activity of the polypeptide of Group IX, are structurally and functionally different chemical compounds, each of which can be made and used without the other compound. The methods of Groups III-V, VIII, and IX require compounds, which are structurally and functionally different from each other, and each can be made and used without the other. Lack of unity is shown because these compounds and the methods utilizing them lack a common utility which is based upon a common technical feature which has been identified as the basis for that common utility.

Further Restriction Within Groups I-IX

4. Whichever Group is elected, further restriction within the elected Group is required to one of the following: One (1) polypeptide and a single (1) corresponding polynucleotide (SEQ that encodes it.

5. The individual polynucleotides, polypeptides, and antibodies which bind said polypeptide do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each polynucleotide and polypeptide represents a structurally and functionally different chemical

compound from each other, which can be made and used without the other compounds, and therefore the antibodies which bind the polypeptides and the compounds which modulate their activity or expression are different, and the methods of using the compounds are also different methods. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

6. **Applicants are advised that this is not a species election.**

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

11. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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April 9, 2008

/Jon M Lockard/
Examiner, Art Unit 1647